

REMARKS

In the Office Action dated October 6, 2004, claims 1-74 are pending. Claims 9, 10, 22, 23, 35, 36, 48-60, 69 and 70 are withdrawn from consideration as directed to non-elected subject matter. Claims 1-8, 11-21, 24-34, 37-47, 61-68 and 71-74 are under examination and are rejected. The application is also objected to for failing to comply with the Sequence Rules.

This Response addresses each of the Examiner's rejections and objections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

The Examiner has made the Restriction Requirement final, and has withdrawn claims 9, 10, 22, 23, 35, 36, 48-60, 69 and 70 from further consideration as directed to non-elected subject matter.

By way of the foregoing amendments, Applicants have canceled these claims without prejudice. Applicants reserve the right to file one or more divisional applications to pursue the subject matter of these claims.

The application is objected to for failing to comply with the Sequence Rules under 37 C.F.R. §1.821(d), specifically, for not identifying the sequence identifiers for the sequences set forth in Figure 16.

In response, Applicants have amended the descriptions of Figures 16A and 16B to insert the relevant sequence identifiers. Support for the amendment is found in the specification, e.g., at pages 16, lines 8-11. No new matter is introduced. Accordingly, the objection to the application based on the Sequence Rules under 37 C.F.R. §1.821(d) is overcome. Withdrawal of the objection is therefore respectfully requested.

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68 and 71-74 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

The Examiner contends that the specification discloses a neocentromere isolated from human chromosome 10, represented by SEQ ID NO: 3. However, the Examiner contends that the specification does not describe any other neocentromere(s), functional derivatives, or other mammalian or non-mammalian homologs that have the same function as the neocentromere represented by SEQ ID NO: 3. Particularly, the Examiner states that the specification fails to describe the structural (i.e. the sequence) that is critical to the function of a neocentromere. It is also the Examiner's opinion that the specification only describes a nucleic acid comprising a neocentromere (SEQ ID NO: 3) of 80 kb. The Examiner states that there is no adequate description of a neocentromere of a length as presently recited, i.e., between 50bp-1500kb, 1kb-1000kb, 10kb-500kb, or 10kb-100kb. Further, regarding claims 5, 18, 31, 44 and 65, the Examiner contends that other than human chromosome mardel 10, the specification does not teach any other modified chromosome from human, or any mammalian or non-mammalian equivalent, that has the same function as the neocentromere of SEQ ID NO: 3. Finally, regarding claims 21, 34, 47 and 68, the Examiner is of the opinion that the specification does not adequately describe a nucleic acid sequence "substantially as set forth in SEQ ID NO: 3", or a nucleic acid sequence "having at least 40% similarity thereto", or a nucleotide sequence "capable of hybridizing to SEQ ID NO: 3 under low stringency conditions at 42°C."

In response to the Examiner's rejection, Applicants have amended independent claims 1, 28 and 61 such that the claims now recite both structural and functional features of

the claimed nucleic acid molecule comprising a neocentromere. More specifically, the claimed nucleic acids are characterized structurally as not having any detectable alpha satellite DNA as determined by fluorescent in situ hybridisation (FISH), at least 80 kb in length and either (i) hybridizes to SEQ ID NO: 3 under high stringency conditions, or (ii) at least 80% identical with SEQ ID NO: 3. The claimed nucleic acids are further characterized functionally as capable of replicating, acting as an extra-chromosomal element and segregating with cell division when introduced into a cell. Support for the recitation that the nucleic acid molecule does not have any detectable alpha satellite DNA as determined by fluorescent in situ hybridisation (FISH), is found in the specification, e.g., at page 13, lines 27-28. Support for the hybridisation conditions and sequence identity language is found in the specification, e.g., at page 16, line 22, and page 17, lines 3-6. Support for a length of "at least 80 kb" is found in the specification, e.g., at page 16, lines 1-5; page 45, lines 11-15. No new matter is introduced.

In addition, Applicants have deleted from the claims recitations relating to a modified chromosome other than human mardel 10 chromosome. In view of the size characteristic of "at least 80 kb", which is presently recited in independent claims 1, 28 and 61, Applicants have also cancelled claims 11-14, 24-27, 37-39 and 71-74, which are drawn to various size ranges of the claimed nucleic acids. Furthermore, the claims as amended do not include the recitations of "substantially as set forth in SEQ ID NO: 3", "having at least 40% similarity thereto", and "capable of hybridizing to SEQ ID NO: 3 under low stringency conditions at 42°C." Rather, the nucleic acids are presently characterized by their capacity to hybridize to SEQ ID NO: 3 under specified high stringency conditions, or by their high sequence identity (80%) with SEQ ID NO: 3. Applicants reserve the right to pursue the

subject matter encompassed by the claims originally filed in a continuation application.

Regarding the Examiner's contention that the specification does not describe any other neocentromere(s) or functional derivatives other than SEQ ID NO: 3, Applicants respectfully submit that in addition to SEQ ID NO: 3 of about 80 kb, the specification also discloses two clones, E8 and F2, which are derived from a human mardel 10 chromosome. These clones contain sequences of the NC-contig region of the mardel chromosome (which corresponds to the HC-contig region of the normal human chromosome 10), as well as additional p' and q' sequences adjacent to the NC-contig region (such as those set forth in SEQ ID NOS: 5-29). Therefore, based on the present teaching, those skilled in the art would be able to envision nucleic acid molecules of at least 80kb that include a neocentromere, other than SEQ ID NO: 3.

Moreover, Applicants respectfully submit that the law does not require a reduction to practice of every aspect of the claimed invention for the purpose of satisfying the written description requirement under 35 U.S.C. §112, first paragraph. As presently recited, the claimed nucleic acids are characterized by both structural and functional features in a manner that fully complies with the written description requirement.

In view of the foregoing, it is respectfully submitted that the written description rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is therefore respectfully requested.

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68 and 71-74 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite.

The Examiner has objected to the use of the following terms in the claims: "derivative", "derived", "hybrid form", "a modified form", "non-human mammalian or non-

mammalian equivalent", "chemical equivalent" and "substantially as set forth". Applicants respectfully submit that the claims, as presently amended, do not include these terms.

Regarding claims 6, 8, 19, 32 and 66, the Examiner objects to the recitation, "the nucleotide sequence corresponds to a region mapping between q24 and q26 on chromosome 10." In response, Applicants have amended the claims to clarify that the nucleic acid "comprises a region between q24 and q26 on chromosome 10."

Regarding claims 4-8, 17-21, 30-34, 43-47 and 64-68, the Examiner objects to the recitation of "capable of associating with centromeric binding protein...". Applicants have amended the claims to clarify that the nucleic acid binds to a centromeric binding protein.

Regarding claims 29-34, the Examiner objects to the recitation of "a compatible cell." Applicants have amended the claims to recite "a cell" instead.

Regarding claims 61-67 and 71-74, the Examiner has objected to the term "defines". Applicants have amended the claims to replace the term "defines" with "comprises".

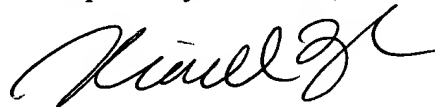
Applicants respectfully submit that the claims as presently amended are not indefinite. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-8, 11-14, 15-21, 24-27, 28-34, 37-39, 40-47, 61-68 and 71-74 are rejected under the judicially created doctrine of double patenting over claims 1-7, 10-15, 18-24, and 27-32 of U.S. Patent No. 6,265,211. The Examiner indicates that the claimed invention and the issued claims are directed to the same subject matter; that the pending claims have a broader scope and thus are anticipated by claims 1-7, 10-15, 18-24, 27-32 of the '211 patent.

Applicants acknowledge that the instant double patenting rejection can be overcome by filing a terminal disclaimer, which will be filed after the Examiner indicates otherwise allowable subject matter in the present application.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Xiaochun Zhu
Registration No. 56,311

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza, Ste 300
Garden City, New York 11530
(516) 742-4343
XZ:ab